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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/444,790	05/19/95	BROCKHAUS	M 9189

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HM12/0425

EXAMINER

MURPHY, J

ART UNIT	PAPER NUMBER
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1644

*24*

DATE MAILED:

04/25/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

**Office Action Summary**

Applicant(s)

08/444,790

Applicant(s)

BROCKHAUS ET AL.

Examiner

Joseph F Murphy

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 July 1998.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 44-46, 56-58, 60 and 61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 44-46, 56-58, 60 and 61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_\_.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

**Attachment(s)**

- 14) ☒ Notice of References Cited (PTO-892)
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 17) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☒ Other: *Sequence Comparison A*.

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### **DETAILED ACTION**

Claims 47 and 59 were canceled, claim 44 was amended, and new claims 60-61 were added in Paper No. 18, 7/14/2000.

Claims 44-46, 56-58 and 60-61 are under consideration.

### ***Response to Arguments***

Applicant's arguments filed in Paper No. 18, 7/14/2000, have been fully considered, and are deemed persuasive in part. Remaining issues, and new issues, are discussed below.

The objection to claims 47 and 59 is moot based upon Applicant canceling these claims.

The rejection of pending claims 44-45 and 56 under 35 USC § 112, first paragraph, as being non-enabled for insoluble proteins which binds TNF has been obviated by Applicant's amendment, and is thus withdrawn.

The rejection of pending claims 44-45 and 56 under 35 USC § 112, second paragraph, for the recitation of the term "insoluble" has been obviated by Applicants amendment, and is thus withdrawn.

The rejection of claims 44 and 46 under 35 USC § 102 over Smith et al. has been withdrawn in light of Applicant's arguments.

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***Claim Objections***

Claim 44 is objected to because of the following informalities:

There should be a space between "polyacrylamide" and "gel",

Claim 61 is objected to because of the following informalities:

The proper three letter code for isoleucine is "Ile" not "Ilein".

Appropriate correction is required.

***Claim Rejections - 35 USC § 112 first paragraph***

The rejection of claims 44, 46, 57 and 58 under 35 USC § 112, first paragraph, for being non-enabled for TNF receptor polypeptides other than those exemplified in the specification has been maintained for reasons of record set forth in Paper No. 15, 11/7/1997.

Claims 44, 46, 57-58 and 60 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Claims 44, 46, 57-58 and 60 define a protein by a function alone, i.e. it acts as a receptor which binds human TNF. However, in *University of California v. Eli Lilly*, 119 F.3 at 1568, 43 USPQ2d at 1406 the Court decided that a definition by function alone "does not suffice" to sufficiently describe a sequence "because it is only an indication of what the gene does, rather than what it is." Further, "it is only a definition of a useful result rather than a definition of what achieves that result...The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention". Applicant has not set forth within the claim the detailed constitution of the receptor protein, and thus does not satisfy the written description requirement.

Claims 46, 57-58 and 60 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for homogeneous protein comprising an amino acid sequence set forth in Figure 1, does not reasonably provide enablement for amino acid sequences that are fragments of said sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 46, 58 and 60 are overly broad in the recitation of "fragment". There is not adequate guidance as to the nature of the fragments which Applicants claim. Since fragments of polypeptides can include single amino acids, the claim can be reasonably interpreted to include any substantially purified polypeptide that is smaller in size than the polypeptide of Figure 1.

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There is no guidance provided in the specification as to the relationship between the structure of the receptor protein and its function. Without this information, it would require undue experimentation for one of skill in the art to generate a homogeneous receptor protein, other than that which is exemplified in the specification. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. The factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill; (5) the level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. Given the breadth of claims 46, 58 and 60 in light of the predictability of the art as determined by the number of working examples, the level of skill of the artisan, and the guidance provided in the instant specification and the prior art of record, it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention. Claim 57 is rejected insofar as it depends on the recitation in claim 46 of "fragment" of a receptor protein comprising an amino acid sequence as set forth in Figure 1.

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***Claim Rejections - 35 USC § 112 second paragraph***

Claims 46, 58 and 60 are indefinite in the recitation of the term "fragment". This language is vague and indefinite since it encompasses potentially any portion of the polypeptide including a single amino acid. There is no guidance provided as to what specific sequences the term "fragment" refers to. Therefore, the metes and bounds of the claim are unclear. Claim 57 is vague and indefinite insofar as it depends on claim 46 for the recitation of "fragment".

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 44-45, 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Olsson et al. (1989).

Olsson et al. discloses the purification to homogeneity of a soluble TNF binding protein. The disclosed protein is 50 kD, as determined by SDS-PAGE (page 273, Figure 3), thus anticipating claim 44. The disclosed protein has a sequence comprising the amino acid sequence set forth in Figure 1 (see Sequence Comparison A, attached, as well as page 274, column 2, first paragraph), thus anticipating claims 45 and 56.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 44-46, 56-58 and 60-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olsson et al. in view of Miles et al. (1989).

The disclosure of Olsson et al. has been set forth, above. The disclosure of Olsson et al. differs from the claimed invention in not isolating the TNF binding protein from host cells producing the recombinant protein. Miles et al. teaches the use of recombinant DNA technology to express cloned genes. Therefore it would have been obvious to one of skill in the art at the time the invention was made to clone the nucleic acid encoding the TNF binding protein, and express the protein in a host cell. The motivation is provided in Miles et al. who teaches that expression of cloned genes allows many different pharmacologically active proteins to be produced on a scale and purity not previously seen.

***Conclusion***

No claim is allowed.



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*Advisory Information*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245.

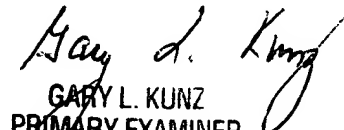
The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703-308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Joseph F. Murphy, Ph. D.  
Patent Examiner  
Art Unit 1644  
April 21, 2000



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